REMARKS

Status of the Claims

Claims 22-24 are pending in this application with claim 22 being the sole independent claim. Claim 22 is sought to be amended.

Amendment after Final Rejection

Applicants believe that the amendment to claim 22, as presented above, will place this application in condition for allowance and/or in better form for consideration on appeal. The purpose of the claim amendment presented above is to more explicitly define the composition of the adjuvant used in the practice of the claimed methods. This amendment does not raise any new issues that would require further consideration and or search and does not raise the issue of new matter (see below). Entry of the above amendment and consideration of the following remarks is respectfully requested.

Support for the Claim Amendment

No new matter is added by way of the claim amendment presented above. Support for the amendment to claim 22 can be found, *inter alia*, in the specification at page 6, lines 3-10.

Claim Objection

Claim 22 was objected to for reciting "SP oil." (Office Action, page 3). The expression "SP oil" is not included in the currently presented claims. Thus, the claim objection is moot.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 22-24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. According to the Office Action, claim 22 is rendered vague and indefinite by the use of the term "SP oil." (Office Action, pages 3-4). The expression "SP oil" is not included in the currently presented claims. Thus, the rejection under 35 U.S.C. § 112, second paragraph is moot and should be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Johnson, Saito and Baylor

Claims 22 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson *et al.* ("Johnson"), Saito *et al.*, U.S. 2005/0158330 ("Saito"), and Baylor *et al.* (2002) *Vaccine 20*:S18-S23 ("Baylor"). (Office Action, page 4). Applicants respectfully traverse this rejection.

The currently presented claims are directed to methods for reducing shedding of *E. coli* O157:H7 in an animal. The claimed methods comprise administering by parenteral injection to the animal an effective amount of a vaccine composition comprising inactivated or killed whole *E. coli* O157:H7, an adjuvant and aluminum hydroxide, and optionally a pharmaceutically acceptable carrier. Claim 22, as currently presented, specifies that the adjuvant is an oil emulsion comprising:

(a) 1% to 3% vol/vol of polyoxyethylene-polyoxypropylene block copolymer;

(b) 2% to 6% vol/vol of squalane;

(c) 0.1% to 0.5% vol/vol of polyoxyethylene sorbitan monooleate; and

(d) buffered salt solution.

None of the cited references, alone or in combination with one another, teach or suggest an oil emulsion comprising the ingredients recited in claim 22.

Johnson refers to an inactivated *E. coli* O157:H7 bacterin supplemented with inactivated verotoxin 2 and intimin$_{O157}$. There is no suggestion that an oil emulsion adjuvant could or should be used in place of, or in combination with, inactivated verotoxin 2 and intimin$_{O157}$.

Saito refers to a water-in-oil-in-water (W/O/W) adjuvant vaccine comprising an outer aqueous phase containing a specific amount of a polyethylene glycol derivative having a specific molecular weight. (*See* Saito, paragraph [0013]). Saito mentions several other categories of ingredients that might be included within the W/O/W adjuvant vaccine. With the benefit of hindsight, and having reference to the teachings of the present application, one could potentially identify in Saito certain ingredients that are also found in the oil emulsion recited in present claim 22.

For example, Saito states that the oil component of the W/O/W adjuvant vaccine can be either an ester oil base or a non-ester oil base (*See* Saito, paragraph [0027]). If a non-ester oil base is selected, Saito provides a list of fifteen different ingredients that can be used: (1) light liquid paraffin, (2) squalene, (3) squalane, (4) polybutene, (5) caprylic acid, (6) capric acid, (7) oleic acid, (8) linolic acid, (9) linolenic acid, (10) peanut oil, (11) olive oil, (12) safflower oil, (13) sunflower oil, (14) jojoba oil and (15) orange roughy oil. After studying Applicants' invention and the disclosure supporting it, a skilled person would notice that one of the items included on this list is also found in the oil emulsion adjuvant of the present invention.

Without the benefit of hindsight, however, a person of ordinary skill in the art would have no reason to select from Saito any of the particular ingredients recited in the present claims, much less the precise combination of ingredients recited in the present claims. Even with the benefit of hindsight, however, the skilled person would still not have been able reconstruct from Saito (or any of the other cited references) the emulsion adjuvant included in claim 22 because there is no suggestion to use the vol/vol percentages that are recited in claim 22 of the present application.

Baylor does not cure the aforementioned deficiencies of Johnson and/or Saito.

MPEP § 2143 sets out seven different exemplary rationales that may support a conclusion of obviousness. As explained below, none of the exemplary rationales apply to the currently claimed invention.

(A) Combining prior art elements according to known methods to yield predictable results. Even if a skilled person were to combine elements of the cited references with one another, a method that falls within the scope of the present claims would not be obtained. In particular, the use of a vaccine composition made from the inactivated *E. coli* bacterin of Johnson, the oil adjuvant of Saito, and the aluminum salts of Baylor would not fall within the scope of the currently presented claims because nowhere in the cited art is it taught or suggested to combine the precise components of the adjuvant oil emulsion recited in claim 22 in the specified percentages.

(B) Simple substitution of one known element for another to obtain predictable results. The present invention cannot be regarded as a simple substitution of one known element for another.

(C) Use of a known technique to improve similar devices (methods, or products) in the same way. Applicants are not aware of any "known techniques" that could be used to improve similar vaccination methods and thereby produce a method that falls within the scope of the currently presented claims. No such "known techniques" have been cited by the Patent Office.

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results. Applicants are not aware of any "known techniques" that, if applied to similar vaccination methods "ready for improvement," would produce a method that falls within the scope of the currently presented claims. No such "known techniques" have been cited by the Patent Office.

(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. The exact combination of components of the oil emulsion recited in claim 22, in the vol/vol percentages specified in the claim, cannot be regarded as an obvious combination derived from a "fine number of identified, predictable solutions."

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. Applicants are not aware of any "known work" in any fields of endeavor that would prompt variations of it that would result in a method that falls within the scope of the currently presented claims. No such "known work" has been cited by the Patent Office.

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. The cited art provides neither a teaching, a suggestion, nor a motivation that would have led a person of ordinary skill to modify the cited references or combine the cited references. As discussed above, even if a skilled person were somehow motivated to combine the cited references, the claimed method would not be obtained in any event.

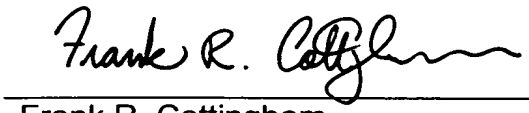
Johnson, Saito, Baylor and Elder

Claims 22-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson, in view of Saito and Baylor, and further in view of Elder *et al.* (2002) *J. Animal Sci. 80*:151, abstract 602 ("Elder"). (Office Action, page 8). Applicants respectfully traverse this rejection for the reasons set forth immediately above. Elder does not cure any of the noted deficiencies of Johnson, Saito and/or Baylor.

Since a *prima facie* case of obviousness has not been established with respect to any of the currently presented claims, Applicants respectfully request that the rejections under 35 U.S.C. § 103 be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants believe that this application is in condition for allowance, and prompt, favorable action thereon is earnestly solicited. If the Examiner believes that any points require additional consideration, the Examiner is invited to contact the undersigned at the telephone number provided below.



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